

Food, Drug and Cosmetic Regulations

Chapter 4, Part I

Shellfish Depuration Regulations

49:6.1230 Depuration - Harvesting Permit

A. Any person, firm or corporation engaging in the business of harvesting shellfish for depuration purposes from areas not approved by the state health officer for direct market harvesting shall be required to have an unsuspended or unrevoked harvesting-for-depuration permit issued by the Department of Health and Hospitals. Growing waters to be utilized for harvesting purposes must meet or exceed the Department of Health and Hospitals' criteria for restricted area classification. A fee of \$50 shall be charged for each 30-day permit.

B. Harvesting-for-depuration permits shall be granted only to responsible individuals with no recent history of illegal harvesting violations under the following conditions:

1. No permittee, vessel captain or crew member may serve on any vessel subject to this permit who has been cited or found guilty of violations relative to the harvesting of shellfish within three years of the application date; provided, however that said permittee, crew member or vessel captain may receive a waiver of this condition with regard to those citations which did not result in a conviction upon the appropriate showing being made to the Department of Wildlife and Fisheries.

2. A \$5,000 cash performance bond consisting of a bank cashier's check or money order made payable to the Department of Health and Hospitals shall be posted by each permittee.

3. Harvesting and transporting of shellfish to depuration plants shall be permitted only during daylight hours with all activities completed no later than 30 minutes after official sunset each day.

4. The permittee shall be responsible for notifying the Department of Wildlife and Fisheries prior to leaving port to fish under permitted conditions and immediately upon returning from permitted trip each day. The Department of Wildlife and Fisheries shall be notified by calling 1-800-442-2511.

5. All leases utilized for harvesting-for-depuration purposes shall be "red flagged" so that they may be easily spotted by both aircraft and boat. "Red flagged", as used in this paragraph, means that the four outside corners of a lease must be marked with poles with red flags attached.

6. The sacking of shellfish and the storage of empty shellfish sacks aboard permitted vessels is prohibited.

7. All harvesting and transporting of shellfish for delivery to a depuration plant shall be done in the direct line of sight of a commissioned municipal, parish, or state police officer, or bonded security guard from a state licensed agency. The payment of the surveillance officers salary and expenses shall be the responsibility of the permittee.

8. A maximum of five harvest boats may be included on one permit under the following conditions:

(a). The permittee, vessel captain and crew members shall all be held liable for rule violations.

(b). All vessels must be in direct line of sight of state approved surveillance officer during harvesting and transporting of shellfish to depuration plant.

(c). Each permitted vessel shall have the permit number in at least 6-inch high letters on a contrasting background so as to be visible from low flying aircraft or from any other enforcement vessel in the immediate area.

9. Failure to comply with any of the permitting requirements specified in this Section shall result in the following administrative actions:

(a). The harvesting-for-depuration permit and all permitting privileges shall be immediately suspended by the Department of Wildlife and Fisheries or the Department of Health and Hospitals.

(b). All shellfish harvested-for-depuration purposes shall be returned to the original growing waters at permittee's expense.

(c). If said charges are upheld in an administrative hearing, the following additional penalties shall be imposed:

1. Harvesting-for-depuration and transplant permitting privileges shall be denied for a period of three years.

2. The \$5,000 cash bond posted by the permittee shall be forfeited and retained by the state.

Rose V. Forrest
Secretary

9408#057

RULE

Department of Health and Hospitals Office of the Secretary

Case Management Licensing Standards (LAC 48:I.Chapter 49)

In accordance with the provisions of R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the Department of Health and Hospitals, Office of the Secretary, under the authority vested in R.S. 28:380-451, adopted the following revised licensing standards for Department of Health and Hospitals (DHH) case management providers. This rule in no way alters the current licensing requirements for Department of Social Services providers.

The purposes of these revisions is to enhance the quality and cost effectiveness of case management services funded through DHH and provided to eligible individuals. This rule supersedes all rules previously promulgated related to licensing of DHH case management only.

Title 48

PUBLIC HEALTH-GENERAL

Part I. General Administration

Subpart 3. Licensing and Certification

Chapter 49. Case Management/Service Coordination

§4901. Personnel Standards

A. Staff qualifications

1. Case managers hired or promoted on or after August

20, 1994 must meet the following criteria for education and experience:

a. a bachelor's degree in a human services related field including but not limited to psychology, education, rehabilitation counseling, or counseling from an accredited institution; and one year of paid experience in a human services field providing direct consumer services or case management or

b. a licensed registered nurse; and one year of paid experience as a registered nurse in public health or a human services related field providing direct consumer services or case management; or

c. a bachelor's or master's degree in social work from a social work program accredited by the Council on Social Work Education;

d. thirty hours of graduate level course credit in a human services related field may be substituted for the one year of required paid experience. Experience may be obtained before or after completion of the degree or obtaining licensure;

e. all case managers must be employees of the provider. Contracting for case managers is prohibited.

2. Case management supervisors hired or promoted on or after August 20, 1994 must meet the following qualifications for education and experience:

a. a master's degree in social work, psychology, nursing, counseling, rehabilitation counseling, education with certification in special education, occupational therapy, speech or physical therapy from an accredited institution; and two years of paid post-degree experience in a human services related field providing direct consumer services or case management; and one year of this experience must be in providing direct consumer services to the targeted population to be served; or

b. a bachelor's degree in social work from a social work program accredited by the Council on Social Work Education; and three years of paid post-degree experience in a human services related field providing direct consumer services or case management. Two years of this experience must be in providing direct consumer services to the targeted population to be served; or

c. a licensed registered nurse; and three years of paid post-licensure experience as a registered nurse in public health or a human services related field providing direct consumer services or case management. Two years of this experience must be in providing direct consumer services or case management to the target population to be served; or

d. a bachelor's degree in a human services field including but not limited to psychology, education, rehabilitation counseling, or counseling from an accredited institution; and four years of paid post-degree experience in a human services related field providing direct consumer services or case management. Two years of this experience must be in providing direct consumer services to the targeted population to be served;

e. thirty hours of graduate level course credit in the human services field may be substituted for one year of experience.

B. Training. Case managers must receive necessary

orientation and periodic training on the provision of case management services arranged or provided through their agency.

1. Orientation of at least 16 hours shall be provided by the agency to all staff, volunteers and students within five working days of employment which shall include, at a minimum:

- a. policies and procedures of the provider
- b. confidentiality
- c. documentation in case records
- d. consumer rights protection and reporting of violations
- e. abuse and neglect policies and procedures
- f. professional ethics
- g. emergency and safety procedures
- h. infection control including universal precautions.

2. For newly hired or promoted case managers who will provide services primarily to a specific population or subgroup, a minimum of eight hours of the orientation training must cover orientation to each target population to be served including but not limited to specific service needs and resources.

3. Routine supervision cannot be considered training.

4. In addition to the minimum 16 hours of orientation, all case managers must receive a minimum of 16 hours of training during the first 90 calendar days of employment which is related to the target population to be served and specific knowledge, skills and techniques necessary to provide case management to the target population. This training must be provided by an individual with demonstrated knowledge of the training topic and the target population. This 16 hours of training must include, at a minimum:

- a. assessment techniques
- b. service planning
- c. resource identification
- d. interviewing techniques
- e. data management and record keeping
- f. communication skills

5. No new case manager employee can be given sole responsibility for a consumer until this training is satisfactorily completed and the employee possesses adequate abilities, skills and knowledge of case management.

6. A case manager must complete a minimum of 40 hours of training per calendar year. For new employees, the orientation training cannot be counted toward the 40 hour minimum annual training requirement. The 16 hours of training for new case managers required in the first 90 days of employment may be counted toward the 40-hour minimum annual training requirement. Appropriate updates of topics covered in orientation and training for a new case manager must be included in the required 40 hours of annual training. The following is a list of suggested additional topics for annual training:

- a. the nature of the illness or disability, including symptoms and behavior
- b. pharmacology
- c. potential array of services for the population/available local resources
- d. building natural support systems

- e. family dynamics
- f. developmental life stages
- g. crisis management
- h. first aid/CPR
- i. signs and symptoms of mental illness, alcohol and drug addiction, and mental retardation/ developmental disabilities, head injuries and/or HIV
- j. recognition of illegal substances
- k. monitoring techniques
- l. advocacy
- m. behavior management techniques
- n. developmental life stages
- o. value clarification/goals and objectives
- p. stress management/time management
- q. accessing special education services
- r. cultural diversity
- s. pregnancy and prenatal care
- t. health management
- u. team building/interagency collaboration
- v. transition/closure
- w. age-appropriate preventive health care
- x. facilitating team meetings
- y. computer skills
- z. legal issues

7. A case management supervisor must satisfactorily complete 40 hours of training per year. A new supervisor must satisfactorily complete a minimum of 16 hours on all of the following topics prior to assuming case management supervisory responsibilities:

- a. professional identification/ethics
- b. process for interviewing, screening, and hiring staff
- c. orientation/in-service training of staff
- d. evaluating staff
- e. approaches to supervision
- f. managing caseload size
- g. conflict resolution
- h. documentation

8. Documentation of all training must be placed in the individual's personnel file. Documentation must include an agenda and the name, title, agency affiliation of the training presenter(s) and other sources of training.

C. Supervision

1. Each case management provider must have and implement a written plan for supervision of all case management staff. Supervision must occur at least once per week per case manager. Supervisors must review at least 10 percent of each case manager's case records each month for completeness, compliance with these standards, and quality of service delivery.

2. Supervision of individual case managers must include the following:

- a. direct review, assessment, problem solving, and feedback regarding the delivery of case management services;
- b. teaching and monitoring of the application of consumer centered case management principles and practices;
- c. assuring quality delivery of services;
- d. managing assignment of caseloads;
- e. arranging for or providing training as appropriate.

3. Supervision must be accomplished by a combination

of more than one of the following means:

- a. individual, face to face sessions with staff to review cases, assess performance and give feedback;
- b. sessions in which the supervisor accompanies an individual staff member to meet with consumers. The supervisor assesses, teaches and gives feedback regarding the staff member's performance related to the particular consumer;
- c. group face to face sessions with all case management staff to problem solve, provide feedback and support to case managers.

4. Each supervisor must maintain a file on each case manager supervised and hold supervisory sessions on at least a weekly basis. The file on the case manager must include, at a minimum:

- a. date and content of the supervisory sessions; and
- b. results of the supervisory case review which shall address, at a minimum, completeness and adequacy of records, compliance with standards, and effectiveness of services.

5. Case managers must be evaluated at least annually by their supervisor according to written policy of the provider on evaluating their performance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: (August 1994).

§4903. Caseload Size Standards

A. Each full-time case manager may only have a maximum of 60 consumers in a caseload unless a lower ratio exists in DHH or other applicable controlling state or federal regulations.

B. Each case management supervisor may only have a maximum of five full-time case managers or a combination of full-time case managers and other human service staff under their direct supervision.

C. A supervisor may carry one-fifth of a caseload for each case manager supervised less than five. For example, a supervisor of three case managers may carry two-fifths of the maximum caseload.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: (August 1994).

§4907. Application Procedure

The applicant shall submit a copy of a request for licensure to the Department of Health and Hospitals, Health Standards Section, P. O. Box 3767, Bin #27, Baton Rouge, Louisiana 70821-3767. The request shall include descriptions of:

- 1. the target populations to be served;
- 2. geographical areas (regions) to be served;
- 3. address(es) of the office site(s) to be used;
- 4. administrative file as described under §4943;
- 5. the provider's policies and procedures manual;
- 6. the requested program and services to be provided as outlined in §4953;
- 7. the provider's plan for staffing as outlined in §4959.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: (August 1994).

§4909. Review of Applications

The complete application request with the required fee must be received by the Health Standard Section at least 60 days prior to the date for which licensing is sought. A written response will be provided to the applicant.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: (August 1994).

§4910. Types of Licenses and Expiration Dates

A. A license must be issued to an agency by geographical location (DHH region) where records and minutes of formal meetings are maintained and staff reports. When an agency has three or more staff providing case management services in another region, the agency must establish an office site in that region and request a separate license for that geographical location (unless these services are provided in parishes contiguous to the region where the agency is licensed).

B. Temporary licenses may be issued to new providers, providers who have substantially changed—either in ownership or in the services offered or in the location of the office site, or to a provider who has an identified licensing deficiency and the provider's license is expiring within 60 days. Temporary licenses expire on the date specified on the license.

C. Regular licenses expire on the date specified on the license, which will be one calendar year from the date of issue.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4911. Issuance of a License

The agency will not be recognized by DHH until the applicant's enrollment by geographical location (region) is approved by DHH Health Standards Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4915. Reapplication

When a provider changes its ownership or makes any substantial changes in the services offered as outlined in §4910 or changes the location of the licensed agency, the provider must reapply for a license, beginning with a request for licensure. In the event of a change of ownership, the old license must be immediately returned to the DHH Health Standards Section. If no such changes have occurred, the regular annual reapplication must be made at least 60 days prior to the expiration of the current license. The application must be on a form prescribed by the DHH Health Standards Section and must be accompanied by the required fee. A license cannot be transferred to any location or provider other than those specified in the license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4917. Refusal, Revocation, and Fair Hearing

A license may be revoked or refused when applicable licensing requirements are not met, as determined by the DHH Health Standards Section. Licensing decisions are subject to appeal and fair hearing in accordance with state law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4919. Terms of the License

If the provider is in compliance with the requirements of these standards, a license as a client care case management provider will be issued by the DHH Health Standards Section along with a letter enumerating that the agency is permitted to provide case management/service coordination.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4925. Licensing Inspections

Licensing inspections must generally be completed annually, but may occur at any time. No advance notice may be given. Licenser must be given access to the provider office site, staff members or consumers, and all relevant files and records. Licenser must explain the licensing process in an initial interview and must report orally on any deficiencies found during the inspection prior to leaving the agency. A written report of findings must be forwarded to the provider. The provider must respond to the deficiencies cited with a plan of corrective action acceptable to the secretary within 15 working days of receipt.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4929. General Waiver

A. The Office of the Secretary of DHH (the secretary) must determine the adequacy of quality and protection in accordance with the provisions of these standards.

B. If, in the judgment of the secretary, application of the requirements stated in these standards would be impractical in a specified case, such requirements may be modified by the secretary to allow alternative arrangements that will secure as nearly equivalent provision of services as is practical. In no case will the modification afford less quality or protection, in the judgment of the secretary, than that which would be provided with compliance of the provisions contained in these standards.

C. At the time of each subsequent revisit, such requirement modification must be reviewed by the secretary and either continued or cancelled.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4931. Case Management/Service Coordination Services

Case management must consist of services to assist consumers in gaining access to the full range of needed services, including medical, social, educational and other

support services. These must be ongoing services which must be accomplished through the following activities.

1. Intake, which must include determination of a consumer's eligibility for case management services as part of a targeted group of consumers and the determination of need for case management services. All consumers must be interviewed within 14 calendar days of referral to the provider.

2. Assessment/reassessment, which must include the collection and integration of formal/professional and informal information concerning a consumer's social, familial, medical, developmental, legal, educational, vocational, psychiatric and economic status, as appropriate, to assist in the formulation of a comprehensive, individualized written service plan.

a. The assessment process must include input from the consumer/guardian, and may include input from family members, friends, professionals, and service providers, as appropriate.

b. The assessment must focus on the individual's strengths and needs. The case manager must make a face-to-face contact with the consumer as part of the assessment process.

c. The consumer's status must be reassessed on an ongoing basis.

3. Service planning, which must include the development of a comprehensive, individualized written plan based on the needs and strengths of the consumer identified during the assessment process.

a. The consumer/guardian must actively participate with the case manager in development of the service plan with input from family members, professionals and service providers, as needed.

b. The objective of service planning must be to promote consistent, coordinated, timely and quality service provision.

c. The service plan must include, at a minimum: consumer strengths and needs; specific measurable goals and objectives with anticipated time-frames.

d. The service plan must be completed within 45 calendar days of the intake interview for case management services.

e. The written service plan must be reviewed at least 90 days to assure goals and services are appropriate to the consumer's needs identified in the assessment/reassessment process.

D. Linkage, which must assure that the consumer has access to and is receiving the most appropriate services available to meet needs as outlined in the service plan. Linkage must include, but is not limited to:

1. contacting the individual's support network including family, neighbors and friends to mobilize assistance for the individual; and

2. locating or assisting the consumer in locating formal and informal service providers;

3. advocacy, which may occur on behalf of the consumer when needed to assure the consumer has access to and receives appropriate services.

E. Monitoring/follow-up, which must include ongoing interaction with the consumer/guardian, family members and

professionals (as appropriate), and service providers to ensure that the agreed upon services are provided in a coordinated and integrated manner and are adequate to meet the needs and stated goals of the service plan. The case manager must make at least monthly face-to-face contacts with the consumer/guardian as part of the linkage and monitoring/follow-up process.

F. Transition/closure, which must be a joint decision made by the case manager, consumer and/or family member, when appropriate. Closure must occur upon completion of all case management goals identified on the service plan except when case management is a required component of a service or a required service.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4933. General Requirements

A. The provider must allow representatives of the state licensing authority, in the performance of their mandated duties, to inspect all aspects of the provider's functioning which impact on consumers and families and to interview any staff member or consumer (if the consumer or family agrees to said interview).

B. The provider must make available to the state licensing authority any information which the provider is required to have under the present requirements and any information reasonably related to assessment of compliance with these requirements.

C. The provider must make available to DHH any information required by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4935. Governing Body

A. The provider must have an identifiable governing body with responsibility for and authority over the policies and activities of the agency.

B. The provider must document, in writing, all members of the governing body; their addresses; their terms of membership; officers of the governing body; and terms of office of any officers.

C. When the governing body does not include consumer and family representation, written policy and procedures must be implemented to ensure consumer and family input.

D. When the governing body is comprised of more than one person, the governing body must hold formal meetings at least semi-annually to discuss agency operations, including programmatic operations.

E. When the governing body is composed of more than one person, the provider must have written minutes of all formal meetings of the governing body and bylaws specifying frequency of meetings and quorum requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4937. Governing Body Responsibilities

The governing body must:

1. ensure the provider's compliance and conformity with its articles of incorporation or charter;
2. ensure the provider's continual compliance and conformity with all relevant federal, state, local and municipal laws and regulations;
3. ensure that the provider shall be adequately funded and fiscally sound;
4. review and approve the provider's annual budget;
5. ensure the review and approval of an annual external audit;
6. designate a person to act as chief administrator and delegate sufficient authority to this person to manage the agency;
7. formulate and annually review, in consultation with the chief administrator, written policies concerning the provider's philosophy, goals, current services, personnel practices, job descriptions and fiscal management;
8. annually evaluate the chief administrator's performance, including evaluation in the areas of quality assurance and disposition of grievances;
9. have the authority to dismiss the chief administrator;
10. notify the designated representatives of DHH prior to initiating any substantial changes in the services provided;
11. ensure that a continuous written Quality Improvement Program is in effect;
12. ensure that services are provided in a culturally sensitive manner as evidenced by staff trained in cultural awareness and related policies and procedures;
13. ensure that all business practices and staff activities conforms to the *Code of Governmental Ethics*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4939. Accessibility of Executive

The chief administrator or a person authorized to act on behalf of the chief administrator must be accessible to staff or designated representatives of DHH during agency hours of operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4941. Documentation of Authority to Operate

A provider must have documentation of its authority to operate under state law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4943. Administrative Files

The provider's administrative files must include at a minimum:

1. documents identifying the governing body;
2. list of members and officers of the governing body, their addresses and terms of membership;
3. minutes of formal meetings and bylaws of the governing body, if applicable;
4. documentation of the provider's authority to operate under state law;

5. functional organizational chart which depicts lines of authority;

6. all leases, contracts and purchase-of-service agreements to which the provider is a party;

7. insurance policies;

8. annual budgets and audit reports;

9. master list of all service providers used by the provider;

10. the provider's policies and procedures

11. Documentation of corrective action taken as a result of external or internal reviews.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4945. Organizational Communication

A. The provider must establish procedures to assure adequate communication among staff to provide continuity of services to the consumer.

B. The provider must establish procedures which facilitates participation and feedback from staff, consumers, families, and when appropriate, the community at large. This will be used in areas such as policy-making, planning, and program development.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4947. Financial Management

A. The provider must establish a system of financial management and staffing to assure maintenance of complete and accurate accounts, books and records in keeping with generally accepted accounting principles.

B. The provider must demonstrate fiscal accountability through regular recording of its finances and an annual external audit conducted by a certified public accountant.

C. The provider must not permit public funds to be paid, or committed to be paid, to any person to which any of the members of the governing body, administrative personnel, or members of the immediate families of members of the governing body or administrative personnel have any direct or indirect financial interest, or in which any of these persons serve as an officer or employee, unless the services or goods involved are provided at a competitive cost or under terms favorable to the provider. The provider shall have a written disclosure of any financial transaction with the provider in which a member of the governing body, administrative personnel, or his/her immediate family is involved.

D. The provider must be capable of reporting fiscal data from July 1 through June 30.

E. The provider must have adequate and appropriate general liability insurance for the protection of its consumers, staff, facilities, and the general public.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4949. Confidentiality and Security of Records

A. A provider must have written procedures for the maintenance, security, and confidentiality of records. This

must include specifying who must supervise the maintenance of records, and who must have custody of records. This procedure must also state to whom records can be released and the procedure for doing so. Records, including consumer as well as administrative, must be the property of the provider and the provider, as custodian, must secure records against loss, tampering, or unauthorized use.

B. Employees of the provider must not disclose or knowingly permit the disclosure of any information concerning the agency, the consumers or his/her family, directly or indirectly, to any unauthorized person.

C. The provider must safeguard the confidentiality of any information from which the consumer or his/her family might be identified, releasing such information only under the following conditions:

1. by court order;
2. by the consumer's written, informed consent for release of information;

a. when the consumer has been declared legally incompetent, the individual to whom the consumer's rights have devolved provides written consent.

b. when the consumer is a minor, the parent or legal guardian provides written consent.

c. in compliance with the Federal Confidentiality Law of Alcohol and Drug Abuse Patients Records (42 CFR, Part 2).

D. A provider must, upon request, make available information in the case records to the consumer or legally responsible person. If, in the professional judgement of the administration of the agency, it is felt that information contained in the record would be damaging to a consumer, that information (only) may be withheld from the consumer except under court order. The provider may charge a reasonable fee for providing the above records.

E. A provider may use material from case records for teaching or research purposes, development of the governing body's understanding and knowledge or the provider's services, or similar educational purposes, provided that names are deleted and other similar identifying information is disguised or deleted.

F. A system must be maintained that provides for the control/location of all consumer records. Consumer records must be located at the licensed site.

G. A system must be maintained that secures all records from unauthorized access and provides reasonable protection against fire, water damage, tampering, and other hazards.

H. A designated staff member must be responsible for the storage and protection of consumer records.

I. There must be a written process by which the consumer may gain access to his/her own records and receive copies upon written request.

J. Consumer records must be available to appropriate state and federal personnel at all reasonable times.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4951. Records - Administrative and Consumer

A. All provider records must be maintained in an

accessible, standardized order and format and must be retained and disposed of in accordance with state laws.

B. A provider must have sufficient space, facilities and supplies for providing effective record keeping services.

C. Upon agency closure, all provider records must be maintained according to applicable laws, rules and regulations.

D. A provider must have a written record for each consumer which must minimally include:

1. identifying data recorded on a standardized form including the following:

- a. name
- b. home address
- c. home telephone number
- d. date of birth
- e. sex
- f. race or ethnic origin
- g. closest living relative
- h. education
- i. marital status
- j. name and address of current employment, school, or day program, as appropriate
- k. date of initial contact
- l. court and/or legal status, including relevant legal documents
- m. names, addresses, and phone numbers of other persons or providers involved with the consumer's service plan. This shall include the consumer's physician;
- n. other identifying data as indicated;
- o. date the information was gathered;
- p. signature of the staff member gathering the information.

2. Interdiction Status. A notation on the inside of the front cover that the consumer has been interdicted if this information is known.

3. Limited health records including a description of any serious or life threatening medical condition of the consumer. This must include a description of any current treatment or medication necessary for the treatment of any serious or life threatening medical condition or known allergies.

E. A provider must ensure that all entries in records are legible, signed by the person making the entry and accompanied by the date on which the entry was made.

F. Entries must be made in consumer records when services are provided to and/or on behalf of consumer in accordance with the following:

1. All entries and forms in the consumer's record that are completed by the provider must be in ink, are legible, be dated, be signed and shall include the functional title of the person making the entry.

2. An error in the consumer's record made by staff must be corrected by drawing a line through the erroneous information. The word "error" must be written beside the correction, and the correction must be initialed.

3. Correction fluid must never be used in a consumer's record.

G. Consumer record material must be organized in a manner which encourages staff to use it as a communication tool.

1. The location of documents within the record must be consistent among all the provider's records.

2. The record must be appropriately thinned so that current material shall be easily located in the record.

H. Each record must document the need for case management services and the following, at a minimum:

1. medical, social, psychiatric, psychological and other pertinent information regarding the consumer's disability, illness, or condition which will document eligibility for case management services for the targeted population;

2. necessary assessments and other information concerning the consumer's medical, social, familial, cultural, developmental, legal, educational, vocational, psychiatric and economic status, as appropriate, to support the initial service plan, and modifications in the service plan;

3. documentation of the need for ongoing case management and other identified services;

4. written service plan signed and dated by the case manager and the consumer and/or guardian shall be placed in the consumer's record;

5. description of all contacts, services delivered and/or action taken identifying the persons involved in service delivery, the date and place of service, the content of service delivery and the duration of the contact;

6. progress notes written at least monthly to document progress towards specified goals;

7. summary of services provided and progress towards goals, as well as the reason for the closure of the case at the time of termination; and,

8. any joint agreement with the consumer for closure.

I. The provider must utilize the tracking and/or data system for the Program Office of the targeted population being served or a comparable system which tracks the same data elements and allows reporting of data to the program office.

J. The provider must sign an agreement with the appropriate Program Office regarding the exchange of consumer-related data.

K. The record must contain at least six months of current information.

L. Information older than six months may be kept in storage but shall be available for review.

M. The records are maintained until audited and all audit questions answered or for three years from the time of payment, whichever is longer.

N. When a consumer transfers to another provider, at a minimum, copies of the following information must be sent to the requesting provider upon receipt of a release of information signed by the consumer:

1. most current service plan;
2. current assessments upon which service plan is based;
3. number of services used in the calendar year; and
4. last quarter's progress notes;

O. A nonredisclosure clause must accompany all information released to the requesting provider on all Office of Alcohol and Drug Abuse consumers;

P. The receiving provider must bear the cost of copying which shall not to exceed the community's competitive copying rate.

Q. A written policy must govern the disposal of consumer records and confidentiality of consumer information must be protected at the time of disposal.

R. A provider must have a written record for each employee which includes:

1. the application for employment and/or resume'
2. references
3. any required medical examinations

4. all required documentation of appropriate status which includes:

- a. valid driver's license for operating provider vehicles or transporting consumers.

- b. verification of professional credentials/certification required to hold the position including the following:

- i. current licensure
- ii. relevant licensure
- iii. relevant education
- iv. relevant training
- v. relevant experience

5. periodic, at least annual, performance evaluations.

6. employee's starting and terminations dates along with salary paid.

S. An employee must have reasonable access to his/her personnel file and must be allowed to add any written statement he/she wishes to make to the file at any time.

T. A provider must not release a personnel file without the employee's written permission except in accordance with state law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4953. Program Description

A. The provider must have a clear, concise written program description, available to the public, detailing:

1. the overall philosophy of the program;
2. the long and short term goals of the program;
3. the types of consumers to be served;
4. the intake and closure criteria;
5. there must be written eligibility criteria for each of the services/programs provided;
6. the services to be provided;
7. a schedule of any fees for service which will be charged to the consumer;
8. a method of obtaining feedback from the consumer regarding consumer satisfaction with services;
9. an inventory of existing resources (both formal and informal) has been completed that identifies services within the geographic area to address the unique needs of the population to be served. This inventory must be updated at least annually;
10. demonstrated evidence that the program coincides with or is in agreement with existing state, regional, and local comprehensive service coordination and planning for the target population.

B. The provider must make every effort to ensure that service and planning for each consumer must be a comprehensive process involving appropriate staff, representatives of other agencies, the consumer, and where appropriate, the legally responsible person, and any other person(s) significantly involved in the consumer's care on an ongoing basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4955. Transportation

A. The provider must ensure that any vehicle used by the agency staff to transport consumers must be properly maintained, inspected, and licensed according to state laws and carries a sufficient amount of liability insurance.

B. Any staff member using a vehicle to transport consumers must be properly licensed to operate that vehicle according to state laws.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4959. Staff Plan and Staff Coverage

A. A provider must have a written plan for recruitment, screening orientation, ongoing training, development and supervision and performance evaluation of staff members.

B. Sufficient staffing must be provided to ensure a safe environment and adequacy of programming with consideration given to the geography of the setting, the number and needs of individuals served, the intensity of services needed. Staff coverage must be documented.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4961. Nondiscrimination

A provider must have a written policy to prevent discrimination and must comply with all state and federal employment practices, laws.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4963. Recruitment

A provider must actively recruit and, whenever possible, employ qualified persons of both sexes representative of the cultural and racial groups served by the provider. This must include the hiring of qualified persons with disabilities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4971. Program Evaluation

A. The provider must develop and implement a continuous Quality Improvement Plan that is designed to objectively assess and improve the quality of services for consumers which includes the following components:

1. the capability to identify, assess, and correct problems, a time line for correction of deficiency and follow-up on the results of corrective action;

2. procedures to allow immediate response to identified problems.

B. Pertinent findings of quality improvement activities must be reported to the governing body, executive/provider director.

C. The chief administrator must have the responsibility for

the implementation and coordination of the quality improvement process. Duties must be specified.

D. Administrative review and any required corrective action must be conducted as required.

E. The Quality Improvement Plan and process must be reviewed at least annually to determine the need for and the mechanisms for improving the plan.

F. A program evaluation system must be maintained to identify the results of services and the effects of services on the consumer which meets the following criteria:

1. measures outcomes of programs and services;

2. regularly measures the progress of the consumers in relation to the program goals; and

3. evaluates post-discharge information, if applicable;

4. information gained from the system must be used to improve the program.

5. there must be a means to determine when performance is less than acceptable which includes the following:

- a. the reasons must be identified when performance falls below the acceptable level;

- b. management must take prompt action to improve program performance to an acceptable level; and

- c. follow-up and monitoring of corrective actions must be performed at specific times with results documented.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4973. Personnel Practices

A. The provider must have written employment and personnel policies which include:

1. job descriptions for all positions, including volunteers and students, that specify duties, qualifications, and competencies;

2. a description of hiring practices, which includes a policy against discrimination based on race, color, religion, sex, age, national origin, handicap, political beliefs, disabled veteran, veteran status or any other nonmerit factor; and

3. a description of procedures for: employee evaluation, promotion, disciplinary action, termination, and hearing of employee grievances.

B. There must be a written grievance procedure that allows employees to make complaints without fear of retaliation.

C. Grievances must be periodically reviewed by the governing body in an effort to promote improvement in these areas.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4975. Abuse Reporting

A. A provider must have abuse reporting procedures which require all employees to report any incidents of abuse or mistreatment be that abuse or mistreatment is done by another staff member or professional, family member, the consumer, or any other person.

B. There must be written policies and procedures regarding abuse and neglect as defined by state and federal law.

1. The requirement that such action, as defined, must be strictly prohibited

2. Reporting Procedures

a. Every agency employee, consultant or contractor who witnesses, learns of, is informed of, or otherwise has reason to suspect that an incident of abuse or neglect has occurred must report such incident in accordance with state Child Protection laws and Adult Protection laws and fully cooperate with the investigation of the incident.

b. Proper authorities in the agency, community, and state must be identified.

c. Every employee must be informed of his or her reporting responsibilities and trained in the procedures for reporting.

3. Any allegations of abuse and neglect by agency personnel must be investigated internally.

a. Individuals under investigation must not be part of the investigation.

b. The Agency takes appropriate disciplinary action in the case of validated abuse.

c. The results of such investigations must be reviewed at an appropriate higher level and reported to the governing body.

d. Appropriate measures must be taken to assure that the individual is protected from further abuse.

4. Every employee, consultant, and contractor must be given a written copy of the agency's policies and procedures on consumer abuse and neglect.

a. Documentation of policy review by each employee must be maintained in the employee's personnel file.

b. Policies and procedures must be made available to others upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4977. Basic Rights

A. All case managers must conform to applicable state laws and DHH policies and procedures relative to consumer rights, including but not limited to those concerning confidentiality of consumer information and grievance procedures and consumer's right to appeal department decisions on service eligibility, planning, and delivery.

B. All case managers must conform to applicable state laws and DHH policies and procedures regarding consumer health and safety including but not limited to those concerning transporting consumers and abuse/neglect reporting.

C. There must be written policies and procedures that protect the consumer's welfare including the means by which the protections will be implemented and enforced.

D. The consumer, consumer's family or legal guardian, where appropriate, must be informed of their rights both verbally and in writing in language the consumer is able to understand.

E. The written policies and procedures, at a minimum, must address the following protections and rights:

1. to human dignity;
2. to acceptance of chosen life style;
3. to impartial access to treatment regardless of race, religion, sex, ethnicity, age or handicap;
4. cultural access is evidenced through provision of:

a. interpretive services

b. translated material

c. use of native language and staff when possible

d. staff trained in cultural awareness

5. access to persons with special needs is evidenced through sign language interpretation and mechanical aids and devices that assist those persons in achieving maximum benefit from services;

6. to privacy;

7. to confidentiality and access to consumer records including:

a. requirement for the consumer's written, informed consent for release of information

b. emergency unauthorized release

c. internal access to consumer records

d. external access to consumer records

e. conditions for consumer access to his/her records

8. to a complete explanation of the nature of services and procedures to be received including risks, benefits and available alternative services;

9. to participate, actively, in services including assessment/reassessment, service plan development, and transition/closure;

10. to refuse specific services;

11. to complaint/grievance procedures;

12. to be informed of the financial aspects of services;

13. to be informed of the need for parental or guardian consent for treatment or services, if appropriate;

14. to manage, personally, financial affairs unless legally determined otherwise;

15. to give informed written consent prior to being involved in research projects;

16. to refuse to participate in any research project without compromising access to services;

17. to protection from harm including any form of abuse, neglect, or mistreatment;

18. to receive services in a safe and humane environment;

19. to receive the least intrusive services appropriate and available;

20. to contact any advocacy resources as needed, especially during grievance procedures;

21. to be informed of the right to freely choose providers from those available.

F. A provider must ensure that consumers are provided all rights available to them be they interdicted or not.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4979. Self-Advocacy

A provider must make every effort to ensure that a consumer understands his/her rights in matters such as access to services, appeal, grievances, and protection from abuse.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4981. Advocacy

A provider must ensure that an advocate is provided to the consumer whenever the consumer rights or desires may be in conflict or jeopardy with the provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

§4983. Grievance Procedures for Consumers

A. A provider must have a written grievance procedure for consumers designed to allow consumers to make complaints without fear of retaliation.

B. Grievances must be periodically reviewed by the governing body in an effort to promote improvement in these areas.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:308-451.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 20: August 1994).

Rose V. Forrest
Secretary

9408#045

RULE

Department of Health and Hospitals
Office of the Secretary
Bureau of Health Services Financing

Narcotics and Controlled Substances (LAC 48:I.3903)

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing has amended the rule concerning narcotics and controlled substances under the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., and pursuant to R.S. 40:961-1036 and 46:51. In 1992, the department adopted a rule governing the licensing and certification of parties authorized to engage in the manufacture, distribution, or dispensing of controlled dangerous substances. This rule removes the provision for the issuance of a temporary license and mandates possession of a permanent license from the applicable governing board prior to issuance of a license by the department for the manufacture, distribution or dispensing of controlled dangerous drugs.

Title 48

PUBLIC HEALTH - GENERAL

Part I. General Administration

Subpart 1. General

Chapter 39. Controlled Dangerous Substances

§3903. Licensing Procedure as follows:

A. - B. ...

1. Temporary licenses/permits shall not be issued.

* * *

G. Practitioners (dentists, optometrists, physicians, podiatrists, veterinarians) must possess a verifiable valid permanent license in good standing issued by the professional governing board of the state of Louisiana of competent

jurisdiction in order to be issued and maintain a Louisiana controlled dangerous substances license.

1. Physicians who possess a verifiable valid permanent license in good standing issued by the Louisiana State Board of Medical Examiners may be issued a controlled dangerous substances license authorizing the prescribing of the following Schedule I Substances, unless restricted by the Board of Medical Examiners, for therapeutic use by patients clinically diagnosed as suffering from glaucoma, symptoms resulting from the administration of chemotherapy cancer treatment, and spastic quadriplegia:

- a. marijuana;
- b. tetrahydrocannabinols;
- c. a chemical derivative of tetrahydrocannabinols.

2. Practitioners who possess a restricted permanent license issued by the governing board of the state of Louisiana of competent jurisdiction may be issued a restricted Louisiana controlled dangerous substances license adhering to the restrictions of their board license.

A Louisiana controlled dangerous substances license shall not be issued to applicants who possess temporary and/or provisional licenses and/or permits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:961-1036 and 46:51.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 18:962 (September 1992), repromulgated LR 18:1132 (October, 1992), amended LR 20: (August 1994).

Rose V. Forrest
Secretary

9408#046

RULE

Department of Health and Hospitals
Office of the Secretary
Medical Disclosure Panel

Informed Consent (LAC 48:I.2400-2428)

As authorized by R.S. 40:1299.40(E), as enacted by Act 1093 of 1990 and later amended by Act 962 of 1991 and Act 633 of 1993, the Department of Health and Hospitals, Office of the Secretary, in consultation with the Louisiana Medical Disclosure Panel, has adopted rules by adding §§2400-2428 to Chapter 23, Informed Consent, requiring which risks must be disclosed under the Doctrine of Informed Consent to patients undergoing medical treatments or procedures and the Consent Form to be signed by the patient and physician before undergoing such treatment or procedure.

Title 48

PUBLIC HEALTH-GENERAL

Part I. General Administration

Chapter 23. Informed Consent

§2400. Esophageal Dilation/Esophagogastroduodenoscopy

- A. Infection;
- B. Bleeding which may require transfusion and/or surgery;